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EXAMINER

LY, CHEYNE D

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/975,530

Applicant(s)

WILKES ET AL.

Examiner

Cheyne D Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on May 06, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-47 and 67-70 is/are pending in the application.
- 4a) Of the above claim(s) 33-47, 67, and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-32, 69 and 70 is/are rejected.
- 7) ☒ Claim(s) 21 and 31 is/are objected to.
- 8) ☒ Claim(s) 20-47 and 67-70 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 6.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. Applicant's election with traversal of Group II, claims 20-32, temperature as the environmental condition, pyrolysis mass spectra as the fingerprint spectrum, and salmonella as the microorganism, in Paper No. 7, filed May 06, 2003, is acknowledged.
2. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search on all the claims of groups I-VII together. This is not found persuasive because each Group is directed to a distinct method that has different active step requirements for achieving their respective intended goals. Further, Applicants traverse that claims II-IV be rejoined and examined together because "the written Restriction Requirement does not establish a prima facie case in support for the restriction." This is also not found persuasive because Group II differ from Group III due to Group III having an active step requirement of detecting a similarity between expected fingerprint spectrum and a library fingerprint of a know organism which is not present in Group II. Further, Group II differ from Group IV because Group IV has an active step requirement of converting the fingerprint spectrum with a transformation algorithm, which is not present in Group II. It is acknowledged that the commonality of all the groups is the data related to fingerprint spectra. However, the distinct intended goal and active steps of each group support the lack of overlapping searches due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.
3. The requirement is still deemed proper and is therefore made FINAL.
4. Applicants' interview summary has been acknowledged.
5. It is acknowledge new claims 67-70 have been added.

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6. Claims 33-47, 67, and 68 have been withdrawn due to being not directed to the elected subject matter.

7. Claims 20-32, 69, and 70, temperature as the environmental condition, pyrolysis mass spectra as the fingerprint spectrum, and salmonella as the microorganism, are examined on the merits.

### **OBJECTIONS**

8. Claims 22 and 31 are objected to due to having non-elected subject matter; therefore, withdrawn from consideration.

9. The title of the invention is not descriptive because the claimed invention is to a method for compensating drift in fingerprint spectra while the title is directed to a microbial identification database. A new title is required that is clearly indicative of the invention to which the claims are directed.

### **CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 20-32, 69, and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Specific to claim 20, the claimed method is directed to the method for compensating drift in fingerprint spectra due to changes in environment factors while the body of the claims recites steps for culturing, measuring, detecting and using the differences. The claim is vague and indefinite because it is unclear what are the metes of the bounds of the claim. Is the said method

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used for just for culturing, measuring, detecting and using the differences? Or the said method is used for compensating, to offset or counterbalance, drift in fingerprint spectra? If so, it is unclear how the method of compensating is achieved in the said claim. Clarification of the metes and bounds is required. Claims 21-32, 69, and 70 are rejected for being directly or indirectly dependent from claim 20.

13. Claim 20, line 9-12, recites the limitation of "detecting differences between the fingerprint...under a second set of environmental factors." There is insufficient antecedent basis for this limitation of a second set of environmental factors in the claim. Claims 21-32, 69, and 70 are rejected for being directly or indirectly dependent from claim 20.

14. Specific to claims 20, lines 4, 5, 9, 17; claim 23, line 6; claim 25, lines 20 and 22; claim 26, line 1; claim 27, line 1; claim 28, line 1; and claim 29, line 12; the term "interest" causes the claims to be vague and indefinite because it is unclear what is being used to determine that an organism is of interest (meeting a specific fingerprint spectra requirement or growing in specific culture media). Clarification of the metes and bounds is required. Claims 21, 22, 24, 30-33, 69, and 70 are rejected for being dependent from claim 20, 23, 25, 26, 27, 28, or 29.

15. Specific to claim 29, line 3, the term "closes" causes the claim to be vague and indefinite because it is unclear what is being used to determine "closes" (physical proximity or relative spectra values). Clarification of the metes and bounds is required.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 20-32, 69, and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodacre et al. (1996) taken with Sockalingum et al. (1998) in view of Cano et al. (US 5,593,883 A).

18. Goodacre et al. discloses a method for correcting pyrolysis mass spectrometry drift using artificial neural networks (Abstract etc.). The method of Goodacre et al. comprises culturing microorganisms and measuring fingerprint spectrum of the said microorganisms (page 275, column 1, lines 33-67 to column 2, lines 1-19). The drift correction is performed by taking the difference of two different spectra and transform the said spectra data (page 276, column 1, lines 11-21). The method is performed using the Unscrambler II Version 4.0 program in MS-DOS 6.2 on a PC (page 273, lines 35-39), as in claims 20, 22, 25, 26, 32, and 69.

19. However, Goodacre et al. does not disclose the limitations of the environmental factor being the difference in temperature, library of culture media, similarity between expected

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fingerprint spectra, the expected spectra is added to a database, and the microorganism as salmonella.

20. Sockalingum et al. discloses a method for rapid screening of microorganisms based on FT-IR spectroscopy (Abstract et al.). The data generated from the said method is kept in a data bank for the rapid identification and characterization of different species (page 261, column 2, line 19 to page 262, column 1, lines 1-4), as in claim 70. The method of Sockalingum et al. comprise culturing *E. coli* for 18 hours at 35<sup>0</sup> C and *P. aeruginosa* for 16 hours at 37<sup>0</sup> C, a library of media of the same batch wherein the media may differ in specific antibiotics and spectra similarity is determined by hierarchical grouping or cluster analysis (page 262, Materials and Methods; page 263, lines 7-9; and Figures 3 and 4), as in claims 21, 23, 24, and 31.

21. Further, neither Goodacre et al. nor Sockalingum et al. discloses that the microorganism used is salmonella.

22. Cano et al. discloses microorganisms such as *Salmonella pullorum* (page column 14, lines 3-4) are biologically active in different environmental conditions such as temperature etc. (column 7, lines 3-16), as in claims 27-30.

23. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the concept emphasized by Goodacre et al. for a more precise and accurate method for identifying pathogenic organisms by correcting for mass spectral drift (Abstract etc.) and improve on the said method to screen for microorganisms by spectra data as taught by Sockalingum et al. One of ordinary skill in the art would be further motivated to partake the concept emphasized by Goodacre et al. for a more precise and accurate method for identifying potentially pathogenic organism (page 271, column 1, lines 28-32) and to improve the method of

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Goodacre et al. and Sockalingum et al. by using the said method for rapidly screening for such pathogenic organisms as salmonella as taught by Cano et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use the method for correcting pyrolysis mass spectrometry drift using artificial neural networks as taught by Goodacre et al. to rapidly screen for microorganisms such as salmonella as taught by Sockalingum et al. and Cano et al.

### **CONCLUSION**

24. NO CLAIM IS ALLOWED.

25. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

28. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.




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6/23/03

  
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PRIMARY EXAMINER